UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CITIZENS FOR CONSUMER JUSTICE, CITIZEN ACTION OF NEW YORK, COLORADO PROGRESSIVE COALITION, CONGRESS OF CALIFORNIA SENIORS, CONNECTICUT CITIZEN ACTION GROUP, FLORIDA ALLIANCE FOR RETIRED AMERICANS, GRAY PANTHERS OF SACRAMENTO, HEALTH CARE FOR ALL, INC., HEALTH ACTION NEW MEXICO, MAINE CONSUMERS FOR AFFORDABLE HEALTH CARE, MASSACHUSETTS SENIOR ACTION COUNCIL, MASSPIRG, MINNESOTA SENIOR FEDERATION, NEW JERSEY CITIZEN ACTION, NEW YORK STATEWIDE SENIOR ACTION COUNCIL, NORTH CAROLINA FAIR SHARE, OREGON HEALTH ACTION CAMPAIGN, OREGON STATE PUBLIC INTEREST RESEARCH GROUP, PENNSYLVANIA ALLIANCE FOR RETIRED AMERICANS, UNITED SENIOR ACTION OF INDIANA, INC., VERMONT PUBLIC INTEREST RESEARCH GROUP, WEST VIRGINIA CITIZEN ACTION, WISCONSIN CITIZEN ACTION, BETTY SICHER, JOAN LEE, JOHN BENNETT, PEARL MUNIC, SUE MILES, and JACK DOUGLAS,

Plaintiffs,

v.

ABBOTT LABORATORIES, INC., ALLERGAN WORLDWIDE, ALPHA THERAPEUTIC CORP., AMERICAN BIOSCIENCE, INC., AMERICAN HOME PRODUCTS CORPORATION, AMGEN INC., ASTRAZENECA US, AVENTIS PHARMA, BAXTER INTERNATIONAL, INC., BAYER CORP., BRISTOL-MYERS SQUIBB CO., CHIRON, DEY, INC., FUJISAWA HEALTHCARE, INC., IMMUNEX CORP., ELI LILLY AND

Case No. 01-12257 PBS

**FIRST AMENDED COMPLAINT**

Jury Trial Demanded

COMPANY, ONCOLOGY THERAPEUTICS NETWORK CORP., PHARMACIA CORP., PHARMACIA & UPJOHN COMPANY, SCHERING-PLOUGH, CORP., SICOR, INC., SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, and TAKEDA CHEMICAL INDUSTRIES LTD.,

Defendants.

Plaintiffs, on behalf of themselves, their constituent members and all others similarly situated allege, upon information and belief, except for paragraphs five through sixteen which are based on personal knowledge, as follows:

## INTRODUCTION

1. Plaintiffs bring this action on behalf of Medicare Plan B beneficiaries – elderly and disabled Americans who, in recent years, have received medical treatment for serious illnesses and disabilities – and their insurers to prevent Defendant pharmaceutical manufacturers ("Defendants") from continuing to unlawfully manipulate the Medicare reimbursement system. By fraudulently inflating price reimbursement allowance rates for high profit-margin drugs, Defendants have caused Medicare Plan B beneficiaries to incur millions of dollars in unnecessary and unlawfully inflated co-payment charges for drug regimens required to treat chronic, life-threatening disease, including cancer, renal failure, pulmonary diseases, and other serious ailments.

2. Medicare requires Plan B recipients to contribute twenty percent (20%) of all charges for benefits covered under the plan in addition to payment of a monthly premium and a yearly deductible. Plaintiffs seek declaratory relief finding that Defendant pharmaceutical manufacturers' practice of grossly inflating and manipulating Medicare Plan B reimbursement allowance rates violates applicable law. Plaintiffs also seek monetary relief to compensate

Medicare Plan B beneficiaries and their insurers for the Defendants' unlawful conduct.

3. This action is brought pursuant to the Declaratory Judgment Act, 28 U.S.C. § 2202, and the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 *et seq.*, by Plaintiffs Citizens for Consumer Justice, Citizen Action of New York, Colorado Progressive Coalition, Congress of California Seniors, Connecticut Citizen Action Group, Florida Alliance For Retired Americans, Gray Panthers of Sacramento, Health Care for All, Inc., Maine Consumers for Affordable Health Care, Massachusetts Senior Action Council, MASSPIRG, Minnesota Senior Federation, New York StateWide Senior Action Council, North Carolina Fair Share, Oregon State Public Interest Research Group, Oregon Health Action Campaign, Pennsylvania Alliance for Retired Americans, United Senior Action of Indiana, Inc., Vermont Public Interest Research Group, West Virginia Citizen Action, Wisconsin Citizen Action, Betty Sicher, Joan Lee, John Bennett, Pearl Munic, Sue Miles and Jack Douglas.

4. This action is brought against each of the named Defendants: Abbott Laboratories, Inc., Allergan Worldwide, Alpha Therapeutic Corp., American Bioscience, Inc., American Home Products Corporation, Amgen Inc., AstraZeneca US, Aventis Pharma, Bayer Corp., Baxter International, Inc., Bristol-Myers Squibb Co., Chiron, Dey, Inc., Fugisawa Healthcare, Inc., Immunex Corp., Eli Lilly and Company, Oncology Therapeutics Network Corp., Pharmacia & Upjohn Company, Pharmacia Corp., Schering-Plough, Corp., SICOR, Inc., Smithkline Beecham Corporation d/b/a/ GlaxoSmithKline, and Takeda Chemical Industries, Ltd., seeking declaratory, monetary and other relief regarding certain business practices common to all Defendants – the artificial and fraudulent inflation of publicized average wholesale prices for Medicare Plan B pharmaceuticals. These practices are unlawful under applicable federal law and violate the rights of Medicare Plan B beneficiaries and their insurers.

5. The pharmaceutical manufacturers each implemented fraudulent schemes by: (i) promulgating so-called "average wholesale prices" ("AWP") for Medicare Plan B Covered Drugs ("Covered Drugs") that bear no relation to actual wholesale prices; (ii) abusing the authority Congress vested in the industry to formulate and publish legitimate and accurate average wholesale prices; (iii) creating artificial and grossly inflated AWP prices for publication in the Red Book, Medi-Span, and Price Alert – the resources used by carriers and clinicians to determine Medicare Plan B reimbursement allowances; (iv) encouraging clinicians to administer drugs with the highest AWP in order to receive the greatest reimbursement allowances; and (v) providing additional incentive to clinicians to administer drugs with high AWPs by consistently and regularly decreasing the clinician's acquisition costs without reflecting the decrease in the listed AWP.

6. Clinicians increasingly profited as the "spread" between the acquisition cost and the AWP grew. Manufacturers, on the other hand, benefited where their product offered the greatest "spread" because demand increased dramatically enabling them to achieve massive sales increases and garner a significant competitive edge over manufacturers of similar drugs.

7. As a result, each pharmaceutical manufacturer developed, managed and maintained a regular and consistent scheme resulting in massive over-pricing of Medicare Plan B medications. Chronically ill and disabled Medicare Plan B beneficiaries and their insurers bore, and continue to bear, the costs associated with Defendants' scheme to illegally manipulate an otherwise legitimate enterprise.

8. Defendants are each liable under RICO, 18 U.S.C. § 1961 *et seq.*, to the proposed class of Medicare Plan B beneficiaries. Each Defendant fraudulently manipulates reimbursement allowances for Medicare Part B covered drugs – a repeated violation of federal

mail and wire fraud statutes. Defendants cause physicians, physician groups and other health care providers – otherwise legitimate "enterprises" within the nomenclature of RICO – to demand artificially inflated prices from the Medicare system and Plan B participants with full knowledge that the Medicare beneficiaries and other end-payors suffer severe financial harm as a direct result of their illegal activities.

9. Defendants have infiltrated an established legitimate business practice by interfering with the ongoing relationship between health care providers and their elderly and disabled patients through coercive and manipulative conduct designed to extort extra revenues by grossly distorting and exaggerating the actual wholesale cost of their products.

10. Defendants intentionally abused the regulatory system to take financial advantage of elderly and disabled Medicare Part B participants and their insurers.

## JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction pursuant to the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. § 1961 *et seq.*, and 28 U.S.C. § 1331.

12. The Court has jurisdiction to fashion declaratory and equitable relief pursuant to the Declaratory Judgment Act, 28 U.S.C. § § 2201 and 2202.

13. Venue is proper within this district under 15 U.S.C. § 22 and 28 U.S.C. § 1391(b) and (c) because Defendants do business in this district, certain acts giving rise to the claims asserted in this Complaint occurred within this district, and some Plaintiffs and members of the Class sustained injury within this district as a result of Defendants' illegal actions.

## PARTIES

Plaintiffs

14. Plaintiff Citizens for Consumer Justice ("CCJ") is a Pennsylvania nonprofit umbrella organization that promotes affordable, quality health care. It is located at Architects

Building, 117 South 17th Street, Ste. 311, Philadelphia, Pennsylvania. During the class period, Plaintiff's members indirectly purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, CCJ has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

15. Plaintiff Citizen Action of New York ("CANY") is a coalition of labor, senior citizen, women's, student, tenant and community organizations that works with community activists for social and economic justice. It is located at 94 Central Avenue, Albany, New York. As an unincorporated association, CANY has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

16. Plaintiff Colorado Progressive Coalition ("CPC") is a statewide nonprofit, multiracial network of groups and individuals united for racial and economic justice since 1996. It is located at 1420 Ogden Street, 1st Floor, Denver, Colorado. During the class period, Plaintiff's members indirectly purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, CPC has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

17. Plaintiff Congress of California Seniors ("CCS") is a nonprofit organization representing over 650,000 Californian senior citizens and their families. It is located at 1228 N Street, Suite 29, Sacramento, California. During the class period, Plaintiff's members indirectly purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, CCS has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

18. Plaintiff Connecticut Citizen Action Group ("CCAG") is a statewide membership organization dedicated to working with people to bring about social, economic and

environmental justice. It is located at 139 Vanderbilt Avenue, West Hartford, Connecticut. During the class period, Plaintiff's members indirectly purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, CCAG has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

19. Plaintiff Florida Alliance for Retired Americans ("FLARA") is a nonprofit umbrella organization formed in 1963 representing over 80 groups of retired Floridians with a cumulative membership of over 80,000 individuals. It is located at 12773 West Forest Hill Blvd., Ste. 1213, Wellington, Florida. During the class period, Plaintiff's members indirectly purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, FLARA has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

20. Plaintiff Gray Panthers of Sacramento ("Gray Panthers") is a non-profit organization devoted to advocating justice and equal access for its members and those who are powerless. It has an address at P.O. Box 19438, Sacramento, California 19348. During the class period, Plaintiff's members indirectly purchased prescription pharmaceuticals manufactured and or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, Gray Panthers has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

21. Plaintiff Health Care For All, Inc. ("HCA") is a non-profit organization devoted to making health care a right of all people. It is located at 30 Winter Street, 10th Floor, Boston, Massachusetts. During the class period, Plaintiff's members indirectly purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by

the illegal conduct alleged herein. As an unincorporated association, HCA has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

22. Plaintiff Maine Consumers for Affordable Health Care ("MCAHC") is a non-profit organization committed to helping the people of Maine obtain affordable, quality health care. It is located at One Weston Court, Level 1, Augusta, Maine. During the class period, Plaintiff's members indirectly purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, MCAHC has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

23. Plaintiff Massachusetts Senior Action Council ("MSAC") is a nonprofit advocacy group for seniors, especially championing health care issues. It has 3,000 individual members and over 60 affiliate organizations. It is located at 565 Warren Street, Boston, Massachusetts. During the class period, Plaintiff's members indirectly purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, MSAC has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

24. Plaintiff MASSPIRG is Massachusetts' largest consumer advocacy group. It is located at 29 Temple Place, Boston, Massachusetts. During the class period, Plaintiff's members indirectly purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, MASSPIRG has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

25. Plaintiff Minnesota Senior Federation ("MSF") is a statewide, nonprofit and nonpartisan organization with 25,000 active members and 400 affiliated organizations,

representing 100,000 individuals in all 87 counties. It is located at 555 Park St., Ste. 110, St. Paul, Minnesota. During the class period, Plaintiff's members indirectly purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, MSF has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

26. Plaintiff New Jersey Citizen Action ("NJCA") is the state's largest independent citizen watchdog. It is located at 85 Raritan Ave., #100, Highland Park, New Jersey. During the class period, Plaintiff's members indirectly purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, NJCA has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

27. Plaintiff New York StateWide Senior Action Council ("StateWide") is a grassroots membership organization made up of individual senior citizens and senior citizen clubs from all parts of New York State. It is located at 275 State Street, Albany, New York. During the class period, Plaintiff's members indirectly purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, StateWide has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

28. Plaintiff North Carolina Fair Share ("NCFS") is a non-profit grassroots organization. It is located at 3824 Barrett Drive, Suite 312, Raleigh, North Carolina. During the class period, Plaintiff's members indirectly purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an

unincorporated association, NCFS has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

29. Plaintiff Oregon Health Action Campaign ("OHAC") is a non-profit public interest organization that works to enable Oregon citizens to become better health care consumers while maintaining affordable health care costs. It is located at 3896 Beverly Avenue, N.E., Building J-6, Salem, Oregon. During the class period, Plaintiffs members indirectly purchased prescription pharmaceuticals manufactured and /or distributed by Defendants and were injured by the illegal conduct alleged here. As an unincorporated association, OHAC has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

30. Oregon State Public Interest Research Group ("OSPIRG") is a non-profit public interest research and advocacy group with 33,000 members throughout the state of Oregon. It is located at 1536 S.E. 11th Street, Portland, Oregon. During the class period, Plaintiff's members indirectly purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, OSPIRG has standing to pursue this action under Fed. R. Civ. P. 17 (b)(1).

31. Plaintiff Pennsylvania Alliance for Retired Americans ("PARA") is a nonprofit, advocacy group committed to promoting affordable healthcare. It is located at 2116 Chestnut St., Philadelphia, Pennsylvania. During the class period, Plaintiff's members indirectly purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, PARA has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

32. Plaintiff United Senior Action of Indiana, Inc. ("USAI") is a nonprofit

advocacy group located at 1920 West Morris St., #246, Indianapolis, Indiana. During the class period, Plaintiff's members indirectly purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, USAI has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

33. Plaintiff Vermont Public Interest Research Group ("VPIRG") has been Vermont's leading watchdog and advocacy group since 1972. It is located at 141 Main Street, Ste. 6, Montpelier, Vermont. During the class period, Plaintiff's members indirectly purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, VPIRG has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

34. Plaintiff West Virginia Citizen Action ("WVCA") is a nonprofit organization devoted to increase the voice of the average citizen in public affairs with an emphasis on health care reform. It is located at 1500 Dixie Street, Charlestown, West Virginia. During the class period, Plaintiff's members indirectly purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated association, WVCA has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

35. Plaintiff Wisconsin Citizen Action ("WCA") is the state's premiere public interest organization with 53,000 individual members and 250 affiliate organizations. It is located at 1202 Williamson St., Ste. B, Madison, Wisconsin. During the class period, Plaintiff's members indirectly purchased prescription pharmaceuticals manufactured and/or distributed by Defendants and were injured by the illegal conduct alleged herein. As an unincorporated

association, WCA has standing to pursue this action under Fed. R. Civ. P. 17(b)(1).

36. Plaintiff Betty Sicher is a citizen and resident of the State of New York and a member of New York StateWide Senior Action Council. She resides at 31 South Rigaud Rd., Spring Valley, New York. During the class period, Sicher's clinician administered her, in the clinician's office, a Plan B covered prescription pharmaceutical manufactured and distributed by Defendants. Sicher, a Plan B participant, or her Medigap insurer paid the 20% co-payment.

37. Plaintiff Joan Lee is a citizen and resident of the State of California and a member of the Gray Panthers of Sacramento as well as the Congress of California Seniors. She resides at 5313 Fernwood Way, Sacramento, California. During the class period, Ms. Lee's clinician administered her, in the clinician's office, a Plan B covered prescription pharmaceutical manufactured and distributed by Defendants. Lee, a Plan B participant, or her Medigap insurer, paid the twenty percent (20%) co-payment.

38. Plaintiff John Bennett is a citizen and resident of the Commonwealth of Massachusetts and a member of Massachusetts Senior Action Counsel. He resides at 15G Mansion Woods Drive, Agawam, Massachusetts. During the class period, Bennett's clinician administered him, in the clinician's office, a Plan B covered prescription pharmaceutical manufactured and distributed by Defendants. Bennett, a Plan B participant, or his Medigap insurer, paid the twenty percent (20%) co-payment.

39. Plaintiff Pearl Munic is a citizen and resident of the State of Minnesota and a member of Minnesota Senior Federation. She resides at 15 East Owatonna Street, Duluth, Minnesota. During the class period, Munic's clinician administered her, in the clinician's office, a Plan B covered prescription pharmaceutical manufactured and distributed by Defendants. Munic, a Plan B participant, or her Medigap insurer, paid the twenty percent (20%) co-payment.

40. Plaintiff Sue Miles is a citizen and resident of the State of New York. She resides at 80 LaSalle St., #5A, New York, New York 10027. During the class period, Miles's clinician administered her, in the clinician's office, a Plan B covered prescription pharmaceuticals manufactured and distributed by Defendants. Miles, a Plan B participant, or her Medigap insurer, paid the twenty percent (20%) co-payment.

41. Plaintiff Jack Douglas is a citizen and resident of the State of New York. He resides at 83-45 Broadway, Apt. 423, Elmhurst, New York 11373. During the class period, Douglas's clinicians administered him, in the clinicians' offices, Plan B covered prescription pharmaceuticals manufactured and distributed by Defendants. Douglas, a Plan B participant, or her Medigap insurer, paid the twenty percent (20%) co-payment.

Defendants

42. Defendant Abbott Laboratories, Inc. ("Abbott") is a corporation organized and existing under the laws of the state of Illinois. Abbott's headquarters are located at 100 Abbott Park Rd., N. Chicago, Illinois. Abbott, one of the world's largest pharmaceutical companies, is in the business of manufacturing prescription medications for clinical distribution by Medicare Plan B providers nationwide. Abbott's revenues for the first half of 2001 were over $7.6 billion.

43. Defendant Allergan, Inc. ("Allergan") is a corporation organized and existing under the laws of the state of California. It is headquartered at 2525 Dupont Drive, Irvine, California. Allergan is in the business of providing eye care and specialty pharmaceutical products for clinical distribution by Medicare Plan B providers nationwide.

44. Defendant Alpha Therapeutic Corporation ("Alpha") is a corporation headquartered at 5555 Valley Blvd., Los Angeles, California. Alpha is a subsidiary of Mitsubishi

Pharma Corporation operating under California law. Alpha is in the business of providing home infusion pharmaceuticals for clinical distribution by Medicare Plan B providers nationwide.

45. Defendant American Bioscience, Inc. ("ABI") is a corporation organized and existing under the laws of California. It is headquartered at 2825 Santa Monica Blvd., Santa Barbara, California. ABI is in the business of manufacturing prescription drugs for clinical distribution by Medicare Plan B providers nationwide.

46. Defendant American Home Products Corporation ("AHP") is the parent company of Wyeth Worldwide and, currently, Immunex. It is organized and exists under the laws of the state of New Jersey and its headquarters are located at 5 Giralda Farms, Madison, New Jersey. American Home Products is one of the largest pharmaceutical and health care product companies in the world. Its annual sales in 2000 exceeded $13.3 billion. Through its subsidiaries, AHP manufactures and distributes prescription drugs for clinical distribution by Medicare Plan B providers nationwide.

47. Defendant Amgen Inc. ("Amgen") is a corporation organized and existing under the laws of the state of California. Amgen is headquartered at Amgen Center, Thousand Oaks, California. Amgen is in the business of manufacturing and distributing prescription pharmaceuticals for clinical distribution by Medicare Plan B providers nationwide. In 2000, Amgen's revenues exceeded $3.6 billion.

48. Defendant AstraZeneca U.S. ("AstraZeneca") is a corporation organized and existing under the laws of the state of Delaware. Its primary offices are located at 1800 Concord Pike, Wilmington, Delaware, 725 Chesterbrook Blvd., Wayne, Pennsylvania, and 50 Otis St., Westborough, Massachusetts. AstraZeneca is in the business of manufacturing and distributing prescription pharmaceuticals for clinical distribution by Medicare Plan B providers nationwide.

49. Defendant Aventis Pharma ("Aventis") is a corporation organized and existing under the laws of the state of New Jersey and operating in more than 120 countries in the world. Its principle place of business in the U.S. is located at 300 Somerset Corporation Blvd., Bridgewater, New Jersey. Aventis is in the business of manufacturing and distributing prescription pharmaceuticals for clinical distribution by Medicare Plan B providers nationwide. In 1999, Aventis's pro forma sales for its pharmaceuticals were $3.3 billion.

50. Defendant Baxter International Inc. ("Baxter") is a corporation organized and existing under the laws of Illinois. It maintains its principal place of business at One Baxter Parkway, Deerfield, Illinois. Baxter manufactures and distributes prescription drugs to clinical administrators. Baxter's annual sales from January 1, 2000 through December 31, 2000 were over $6.8 billion.

51. Defendant Bayer Corporation ("Bayer") is a highly diversified health care company whose principal business is the development, manufacture and sale of health care products and services, including pharmaceuticals. Bayer conducts extensive business, including the sale of pharmaceuticals that are the subject of the AWP Scheme alleged herein. Bayer AG is the parent company of Bayer, the subsidiary in the United States that sells and markets Medicare covered prescription drugs to clinicians nationwide. Bayer is located at 100 Bayer Rd., Pittsburgh, Pennsylvania, 15205-9741.

52. Defendant Bristol-Myers Squibb Co. ("Bristol-Myers") is a corporation organized in Delaware with a principal place of business located at 345 Park Avenue, New York, New York. Bristol-Myers manufactures and distributes prescription drugs that are clinically distributed by Medicare Plan B providers nationwide. Bristol-Myers' sales for the year 2000 were more than $21 billion worldwide.

53. Defendant Chiron ("Chiron"), a Bayer subsidiary, is a corporation organized and existing under the laws of the state of California. Chiron's corporate headquarters are located at 4560 Horton Street, Emeryville, California. Chiron manufactures and distributes prescription drugs to Medicare clinical administrators. Revenues for 2000 were $972 million.

54. Defendant Dey, Inc. ("Dey") is a Delaware corporation with its principle place of business at 2751 Napa Valley Corporate Drive, Napa, California. Dey is a specialty pharmaceutical company focused on the development, manufacturing and marketing of prescription drugs used in the treatment of selected respiratory diseases and allergies. Dey, one of the largest U.S. manufacturers of such pharmaceuticals, had net sales of $266 million in 1998.

55. Defendant Fujisawa Healthcare, Inc. ("Fujisawa") is a corporation organized and existing under the laws of the state of Illinois, with its principal place of business located at Parkway North Center, Three Parkway North, Deerfield, Illinois. Fujisawa is a subsidiary of Fujisawa Pharmaceutical Co., Ltd, headquartered in Osaka, Japan. Fugisawa develops and manufactures prescription drugs clinically distributed by Medicare Plan B providers nationwide.

56. Defendant Immunex Corporation ("Immunex"), currently a Bayer subsidiary, is a corporation organized and existing under the laws of the state of Washington. Its principal place of business is located at 51 University Street, Seattle, Washington. Immunex develops and manufactures prescription drugs for clinical distribution by Medicare Plan B providers nationwide. Immunex's total revenues for 1999 were $542 million.

57. Defendant Eli Lilly and Company ("Lilly") is a corporation organized and existing under the laws of Indiana. Its worldwide headquarters are located at Lilly Corporate Center, Indianapolis, Indiana. Lilly is in the business of manufacturing prescription drugs for clinical distribution by Medicare Plan B providers nationwide.

58. Defendant Pharmacia & Upjohn Company ("P&U") is a subsidiary of Pharmacia Corp. In 1995, Pharmacia & Upjohn was formed through the merger of Pharmacia AB and The Upjohn Company. Pharmacia & Upjohn became a global provider of human healthcare products, animal health products, diagnostics and specialty products. In 1998, Pharmacia & Upjohn relocated its global headquarters from the United Kingdom to New Jersey (USA). In September 1999, the company established its global headquarters on a 70-acre campus in Peapack, New Jersey. This site is now the management and pharmaceutical headquarters for Pharmacia Corporation.

59. Defendant Pharmacia Corp. ("Pharmacia") is a corporation organized and existing under the laws of the state of New Jersey. Pharmacia was created through the merger of former Monsanto and Defendant Pharmacia & Upjohn on March 31, 2000. Pharmacia's corporate headquarters are located at 100 Route 206 North, Peapack, New Jersey. Pharmacia manufactures prescription drugs for clinical distribution by Medicare Plan B providers nationwide.

60. Defendant Schering-Plough, Corp. ("Schering-Plough") is a corporation organized and existing under the laws of the state of New Jersey. Its headquarters are located at 2000 Galloping Hill Rd., Kenilworth, New Jersey. Schering-Plough manufactures prescription drugs for distribution by Medicare Plan B providers nationwide.

61. Defendant SICOR, Inc. ("SICOR") is a Delaware corporation organized and existing under the laws of California. Its principal place of business is located at 19 Hughes, Irvine, California. SICOR manufactures injectable pharmaceutical products for distribution by Medicare Plan B providers nationwide.

62. Defendant Smithkline Beecham Corporation d/b/a GlaxoSmithKline ("GSK")

is a corporation organized and existing under the laws of the state of Pennsylvania. It is located at One Franklin Plaza, Philadelphia, Pennsylvania. GSK manufactures prescription drugs for clinical distribution by Medicare Plan B providers nationwide. GSK's research division is located at 5 Moore Drive, Research Triangle Park, North Carolina.

63. Defendant Takeda Chemical Industries LTD ("Takeda") is headquartered in Osaka, Japan with U.S. headquarters located in Lincolnshire, Illinois. Takeda is one of the world's largest pharmaceutical manufacturers. Its 1999 net sales exceeded $8.7 billion. Takeda develops and manufactures prescription drugs for clinical distribution by Medicare Plan B providers throughout the United States.

64. The acts charged in this complaint as having been done by the Defendants were authorized, ordered, or done by its officers, agents, employees, or representatives while actively engaged in the management of the Defendants' business or affairs.

65. Various other individuals, partnerships, sole proprietors, business entities, companies and corporations, presently unknown to Plaintiffs and not named as Defendants in this complaint, participated as co-conspirators in the violations alleged in this complaint and performed acts and made statements in furtherance thereof. Such unknown persons or entities acted as co-conspirators and aided, abetted or participated with Defendants in the commission of the wrongful acts alleged in this complaint.

## FACTS

The Medicare Insurance Program

66. In 1965, Congress enacted Title XVIII of the Social Security Act (the "Act") to pay for the cost of certain medical services for the specific purpose of providing a coordinated and comprehensive approach to federal health insurance and medical care for the aged and

disabled. The Act and its associated programs, usually called "Medicare," is codified at 42 U.S.C. § 1395, *et seq.*

67. As a general rule, the Medicare Program does not pay for most prescription pharmaceuticals, such as drugs that a Medicare beneficiary self-administers by swallowing in liquid or pill form.

68. Medicare Part B allows for payment of the cost of only certain covered drugs ("Covered Drugs.") Covered Drugs include the following: (i) drugs that must be administered by a health care provider; (ii) drugs needed to facilitate the use of covered durable medical equipment; (iii) certain immunizations; and (iv) some self-administered drugs usually relating to cancer or immunosuppressant therapy.

69. Congress crafted Medicare Part B to provide supplementary medical insurance for individuals aged 65 or older, those who are disabled, and individuals suffering from end-stage renal failure. Participation in Medicare's Part B program is voluntary and participants pay a monthly premium, a yearly deductible and a twenty percent co-pay for each covered drug treatment. Medicare Part B is not an entitlement program; participants pay premiums and a substantial co-pay for physician services and Covered Drugs.

70. Although the U.S. Department of Health and Human Services ("HHS") is ultimately responsible for the funding, administrating and supervising of the Medicare program, Congress specifically created a program to administer Medicare through contracts with organizations experienced as third party health care services payors. Under Medicare Plan B, these contractors are called "carriers." A division of HHS, the Health Care Financing Administration ("HCFA"), is responsible for ensuring that the carriers comply with Medicare program regulations and requirements.

71. Carriers reimburse allowable costs for Plan B medications using regulatory formula based on the average wholesale price ("AWP") calculated and published by the pharmaceutical industry. The allowed amount to be paid for a drug under Medicare is determined under the payment methodology set forth in 42 C.F.R. 405.517.

72. From January 1, 1992 to November 2, 1998, under 42 C.F.R. 405.517, drugs and biologicals furnished incident to a physician's service and drugs furnished by an independent dialysis facility were paid based on the lower of the estimated acquisition cost or the national average wholesale price of the drug. During this time the estimated acquisition cost was determined based on surveys of the actual invoice prices paid for the drug. In calculating the estimated acquisition cost of a drug, carriers are permitted to consider factors such as inventory, waste and spoilage. 42 C.F.R. 405.517(b); 56 Fed. Reg. 59621.

73. Payment for multiple source drugs was formulated based on the lower of the estimated acquisition cost or the wholesale price defined as the median price for all sources of the generic drug. 42 C.F.R. 405.517(c); 56 Fed. Reg. 59621.

74. On November 2, 1998, HHS amended the applicable regulations to include drugs or biologicals furnished in conjunction with durable medical equipment. 42 C.F.R. 405.517; 63 Fed. Reg. 58905. The regulation which was published in the Federal Register on November 25, 1991 and became effective on or about January 1, 1992 as amended at 63 Fed. Reg. 58849 provides:

> § 405.517 Payment for drugs and biologicals that are not paid on a cost or prospective payment basis.
>
> (a) Applicability. Payment for a drug or biological that is not paid on a cost or prospective payment basis is determined by the standard methodology described in paragraph (b) of this section. Examples of when this procedure applies include a drug or biological furnished incident to a physician's service, a drug or biological furnished by an independent dialysis facility that is not

> included in the ESRD composite rate set forth in § 413.170 (c) of this chapter, and a drug or biological furnished as part of the durable medical equipment benefit.
>
> (b) Methodology. Payment for a drug or biological described in paragraph (a) of this section is based on the lower of the actual charge on the Medicare benefits or 95 percent of the national average wholesale price of the drug or biological.
>
> (c) Multiple-source drugs. For multiple-source drugs and biologicals, for purposes of this regulation, the average wholesale price is defined as the lesser of the median average wholesale price for all sources of the generic forms of the drug or biological or the lowest average wholesale price of the brand name forms of the drug or biological.

75. Since 1998, payment allowances for drugs and biologicals have been reimbursed by the Medicare Program based on the lower of the actual billed charge or 95 percent of the AWP reflected in pharmaceutical industry publication sources such as the Red Book or Medi-Span. HHS Program Memorandum AB-99-63.

76. Medicare Part B reimburses medical providers 80% of the allowable reimbursable amount. The Medicare beneficiary, or his or her Medigap insurer, pays the additional 20% (the "co-payment"). Each enrollee incurring expenses for benefits and services covered under Medicare Part B is entitled to recover from the program, or have the program pay directly to the health care provider, 80 percent of the reasonable charges for the covered services. Where a health care provider elects to accept payment directly from the program, it may not charge the individual enrollee more than 20 percent of the reasonable cost of the Covered Drug or biological. 42 U.S.C. §§ 1395(j) – 1395(w-4).

77. Medicare Plan B carriers rely on the AWP published in pharmaceutical industry publications, such as the Red Book, Medi-Span, and Price Alert, to ascertain the allowable Medicare reimbursement amount.

78. Ostensibly the industry publications provide objectively verifiable average

wholesale price figures for Medicare Covered Drugs that support the industry's allegations that the stated prices are indeed "average" prices at a "wholesale" level of distribution.

Investigations Into Industry Pricing Practices

79. Over a period of at least five years, the Office of the Inspector General of the Department of Health and Human Services ("OIG"), the Department of Justice ("DOJ"), the National Association of Medicaid Fraud Control Units ("Medicaid Fraud Units") and Group Purchasing Organizations ("GPOs") have investigated the pharmaceutical industry pursuant to widespread allegations of the industry's fraudulent inflation of reimbursement allowance rates for pharmaceutical products, including Medicare Covered Drugs.

80. In connection with these investigations, among other things, these agencies compiled data from drug wholesalers' catalogs for approximately 400 national drug codes representing about 50 different chemical compounds. This data suggests that the industry has abused the privilege designated to them by Congress to set and publicize an "average" wholesale price. In fact, the data reveals that pharmaceutical manufacturers artificially and grossly inflate the true average wholesale prices for Medicare Covered Drugs.

81. The AWPs published by Defendants with the knowledge that they would be used by Medicare-contracted carriers to determine reimbursement allowances, bear little or no resemblance to actual wholesale prices available to the health care providers who bill for these drugs.

82. Each Defendant controls the published AWP for its products and has regularly and unjustifiably raised the AWP in order to capture and control market share and massively increase gross product sales.

83. As a corollary to raising or maintaining artificially high "average wholesale

price" reporting, when true actual wholesale costs decline, Defendants fail to reflect the decline in the published wholesale price. In fact, each Defendant either maintains or raises the AWP as acquisition rates decrease in order to entice clinicians to purchase that Defendant's product.

The 1997 OIG Report

84. At least as early as 1997, the OIG and certain Congressional subcommittees began investigating the Defendants and other pharmaceutical manufacturers for questionable practices regarding the industry's calculation of the AWP. The OIG compared Medicare reimbursement for twenty-two of Defendants' Plan B prescription drugs with the cost of acquiring the same drugs through sources other than through the Defendants in 1996.

85. The OIG concluded that Medicare reimbursement, for these twenty-two drugs alone, exceeded the actual wholesale prices by $447 million. In the same study, the OIG also found that Medicare would have saved $445 million on the same twenty-two drugs in 1995. Of these twenty-two drugs, the OIG found that Medicare had paid twice the actual wholesale price for about one-third of them.

The 1998 OIG Report

86. In 1998, the OIG reviewed drug costs in the Department of Veteran Affairs ("VA") as compared to Medicare costs for the same drugs. The OIG focused on the 34 drugs that had each cost Medicare Plan B at least $10 million in 1996.

87. The 1998 Report concluded that if Medicare had purchased these drugs at the same rates paid by the VA, Medicare and its beneficiaries would have saved $1.03 billion in 1998 on these 34 drugs alone. Medicare would have saved at least 40 percent of the reimbursable allowance for almost half the 22 drugs, and 93 percent for one particular drug, had it been charged marketplace prices for those drugs.

The 2000 DOJ Price Investigation

88. During 2000, the DOJ accumulated price data from a number of wholesale drug catalogs. It provided the data to First DataBank to compile for use by the pharmaceutical industry in calculating its AWP.

89. In September 2000, HCFA authorized Medicare carriers to use the prices compiled by First DataBank in reimbursing Plan B claims.

90. In November 2000, however, HCFA rescinded the order apparently as a result of pressures placed on the legislature and the administration by health care providers and the pharmaceutical industry.

91. As a result, in December 2000, Congress passed legislation requiring the General Accounting Office ("GAO") to complete a more comprehensive study before permitting HCFA to put in place the lower reimbursement rates.

Further OIG Investigations

92. After HCFA required its carriers to establish new Plan B reimbursement allowances, the OIG conducted a study comparing the Medicare allowable amount for 24 drugs to the amount reimbursable under Medicaid and the VA. These drugs represented 79% (or $3.1 billion) of the $3.9 billion in total Medicare drug charges for 1999.

93. The OIG concluded that Medicare and Medicare beneficiaries would have saved $1.6 billion in 1999 if they had paid the same price for the 24 drugs that the VA paid. It also concluded that Medicare reimbursement rates were fifteen to ninety-one percent greater than the prices paid by the VA. The OIG's analysis of the AWP list lead to the conclusion that in the year 2000, Medicare paid at least $887 million more than the *actual* wholesale prices available.

94. This vast overpayment resulted from the Defendants' manipulation of the

reimbursement based on the pharmaceutical industry's published AWPs.

The September 2001 GAO Report

95. In September 2001, the GAO reported to the Commerce Committee that Medicare had paid a grossly disproportional amount for Plan B pharmaceuticals as compared to the providers' true acquisition costs.

Other Congressional Investigations

96. In early 1999, the U.S. House of Representatives Committee on Commerce ("Commerce Committee") began to investigate the prices Medicare pays for Covered Drugs. Over the course of the investigation, the committee staff reviewed almost 100,000 pages of internal drug manufacturers' documents relating to pricing.

97. Congressional investigations evidence that Defendants have reported and published artificially inflated reimbursement allowance rates and manipulated these prices as a component of Defendants' sales and marketing efforts aimed at healthcare providers in order to induce those providers to rely exclusively on Defendants' products.

98. Congressional investigations also indicate that Defendants' reported wholesale prices are monumentally higher than the amounts clinicians actually pay for the drugs. As a result, Medicare beneficiaries, their insurers and American taxpayers pay far more than the true average wholesale price that Congress intended them to pay. Indeed, Medicare and Medicare beneficiaries pay more for Plan B pharmaceuticals than any other consumer group in the U.S.

99. In a September 28, 2000 letter from the House of Representation Committee on Wage and Means, Subcommittee on Health, Congressman Pete Stark has stated that the Defendants' "corruptive scheme is perverting financial integrity of the Medicare program and

harming beneficiaries who are required to pay 20% of Medicare's current limited drug benefit."

100. Congressman Stark made the following five "showing conclusions":

> First – Certain drug manufacturers have abused their position of privilege in the United States by reporting falsely inflated drug prices in order to create a *de facto* improper kickback for their customers.
>
> Second – Certain drug manufacturers have routinely acted with impunity in arranging improper financial inducements for their physicians and other healthcare provider customers.
>
> Third – Certain drug manufacturers engage in the fraudulent price manipulation for the express purpose of causing federally funded health care programs to expend scarce tax dollars in order to arrange de facto kickbacks for the drug manufacturers' customers at a cost of billions of dollars.
>
> Fourth – Certain drug manufacturers arrange kickbacks to improperly influence physicians' medical decisions and judgments notwithstanding the severely destructive effect upon the physician/patient relationship and the exercise of independent medical judgment.
>
> Fifth – Certain drug manufacturers engage in illegal price manipulation in order to increase utilization of their drugs beyond that which is necessary and appropriate based on the exercise of independent medical judgment not affected by improper financial incentives.

101. On September 21, 2001, Congressman Stark observed that according to the OIG, Defendants' illegal abuse of the Medicare Plan B formulary costs Medicare and Medicare beneficiaries as much as $1.9 billion annually.

102. Because Plan B beneficiaries pay a 20% co-payment, the elderly and disabled pay approximately $400 million per year in excessive costs for pharmaceuticals that they depend on. In addition, Plan B beneficiaries have no means of securing an adequate substitute or alternative medications.

Defendants' Fraudulent Marketing Scheme

103. Because Defendants could establish false "average" wholesale prices by posting them in pharmaceutical industry publications, Defendants could charge administering clinicians substantially less than those published prices. The lower the acquisition cost, and the higher the reimbursement allowance, the greater the "spread" between the two and, the greater the clinician's financial incentive (profit) to prescribe Defendants' Covered Drugs.

104. As part of Defendants' scheme to induce health care providers to prescribe the drugs they manufacture, Defendants grossly exaggerated the AWP for Covered Drugs and sold these drugs to providers at a fraction of the so-called average wholesale price. Thus, the "spread" between the providers' acquisition cost and the allowable reimbursement rate – a fiction created by the Defendants – acted as an incentive to providers to prescribe Defendants' products and discouraged use of less-costly alternative medications.

105. Defendants' scheme induced clinicians to prescribe based not on efficacy or the individualized needs of the Medicare beneficiary, but on profit and greed alone.

106. Defendants marketed this scheme in order to massively increase their overall sales as well as to capture and maintain market share.

107. The execution of this scheme of fraudulent incentives was an interstate endeavor intentionally carried out by Defendants' employees. Widespread, interstate cooperation of clinicians, with Defendants' marketing and sales representatives was also a necessary component of Defendants' fraudulent incentive scheme.

108. Defendants also have made available directly to health care providers many other financial inducements to stimulate sales of Covered Drugs at the expense of Plaintiffs and the Class. These inducements include volume discounts, rebates, off-invoice pricing, and

free goods such as gifts of cash and other items of value. The Defendants used these incentives to persuade providers to prescribe Defendants' products exclusively. Each Defendant thereby falsely and illegally captured and/or maintained a greater market share for its Covered Drug.

Defendants' Use of the Mails and Wires in Furtherance of the Scheme

109. Defendants' illegal conduct and practice was carried out by an array of employees, working across state boundaries, who necessarily relied upon the frequent transfer of information and funds by mail and wire.

110. Because Defendants' conducted their pervasive fraudulent market manipulation from their individual headquarters, Defendants, by necessity, required the use of the United States mail and wires to communicate with district managers, located in every state. These district managers oversaw the daily communication between sales representatives and clinicians.

111. Defendants' conduct included mailing and transmitting, (via interstate wires), numerous marketing and sales materials relating to Covered Drugs, Medicare reimbursement allowances and increased profit margins garnered by clinicians in prescribing the Defendants' products.

112. Defendants also used the mail and wires to publish and promulgate the AWP amounts listed in industry publications, as well as to arrange illegal financial incentives discussed herein.

113. Defendants also used the mail and wires to promulgate through industry publications the information clinicians require in order to collect reimbursement under Plan B.

The Fraudulent Scheme as Exemplified by Defendant Dey's Conduct

114. According to Congressional and government agency investigations,

Defendant Dey has consistently engaged in an ongoing, prolonged and deliberate scheme to inflate AWPs.

115. Dey manufactures albuterol sulfate. Albuterol is a drug commonly used with a nebulizer to treat patients suffering from asthma, emphysema and other chronic pulmonary diseases. Medicare spent approximately $246 million for albuterol in 1999 – a figure that represents *nearly half* of the $545 million allowed for all nebulizer-type drugs in 1996.

116. The OIG determined in 1996 that Dey listed the AWP for albuterol sulfate as $.42 per milligram.

117. The OIG, upon independent investigation, found, however, that average wholesale prices for albuterol ran between $.15 to $.21 per milligram. The published AWP represented at least a 100% increase over the actual wholesale prices charged by Dey.

118. In addition, the GAO reported that albuterol sulfate was one of a small number of products accounting for a disproportionately large amount of Medicare Plan B spending and volume of sales.

119. Albuterol ranked fifth in total spending out of over 400 Covered Drugs and accounted for 6.3% of overall Medicare spending.

120. The DOJ concluded that Dey had fraudulently inflated the AWP for albuterol and three other Plan B medications: acetylcysteine, cromolyn sodium, and metaproterenol sulfate.

121. The VA paid millions of dollars less per year for albuterol than Medicare and Medicare beneficiaries. Medicare reimbursed almost seven times the amount paid by the VA. Through the Federal Supply Schedule, the VA paid only $.07 per milligram of albuterol; Medicare reimbursed clinicians – based on Dey's published AWP – at $0.42 per mg.

122. A June, 2000 OIG report found that Medicare would have saved between $47 million and $209 million per year by lowering its reimbursement amount for albuterol to prices available through other sources. Approximately 20 percent of these savings would directly benefit Medicare beneficiaries through reduced co-payments.

123. Dey's spread for albuterol drastically increased during a seven year period between 1992 and 1998. Clinicians' profited progressively from year to year with a peak spread of 67%. The following is an attachment from a letter dated September 25, 2000 by the Chairman Committee on Commerce Tom Bliley to Nacny-Ann Min DeParle regarding Medicare drug pricing manipulation:

**Percentage of "Spread" Between Dey Lab's Reported AWP and the Actual Wholesale Price for Albuterol Sulfate 0.083%**

NDC# 49502-0687-03, 3ml/25's

| Year | Red Book/First Data Bank AWP | McKesson Wholesale Price | Percent "Spread" |
|---|---|---|---|
| 1992 | $32.30 | $25.45 | 21.3% |
| 1993 | $30.25 | $25.39 | 16.1% |
| 1994 | $30.25 | $23.69 | 21.7% |
| 1995 | $30.25 | $15.26 | 49.6% |
| 1996 | $30.25 | $15.26 | 49.6% |
| 1997 | $30.25 | $11.84 | 60.9% |
| 1998 | $30.25 | $10.00 | 67.0% |

Defendants Aventis and Pharma's Manipulation of the AWP

124. Defendants Aventis and Pharma (successors to Hoescht) engaged in an ongoing, prolonged and deliberate scheme to artificially inflate the AWP for Covered Drugs, thereby defrauding Medicare and Medicare Plan B beneficiaries.

125. Aventis and Pharma manufacture Gammar®, an immune globulin used in the treatment of hemophilia. In 1996, Aventis and Pharma listed the AWP for Gammar® as $42.21. Independent investigation by the OIG revealed that the average wholesale prices available to all other consumers of Gammar® -- all non-Medicare Plan B participants – ran